

**2. RESPONSE/REMARKS**

**2.1 STATUS OF THE CLAIMS**

*Claims 1, 3-13, and 15-28 were pending at the time of the Action.*

*Claims 18 and 20-23 were withdrawn from consideration as being directed to a non-elected invention.*

*Claims 3-13, 16-17, 19, 24-28 have been amended herein.*

*Claim 15 has been canceled herein without prejudice and without disclaimer.*

*Claims 29-37 have been added herein.*

*Claims 1, 3-13, and 16-37 remain pending in the application.*

**2.2 SUPPORT FOR THE CLAIMS**

Support for the pending claims can be found throughout the original specification, claims, and figures as filed. Applicants certify that no new matter is included by entry of the present amendment.

Should any fees be deemed necessary in connection with entry of the amendment, the Commissioner is hereby authorized to deduct any necessary amounts from Deposit Account No. 08-1934, Order No. 36677.11.

**2.3 REQUEST FOR CONTINUED EXAMINATION (RCE)**

The present RCE is filed within the statutory six month period after the Final Action and is timely in light of the enclosed request for extension of time and fees.

**2.4 OBJECTION TO CLAIM 12 IS OVERCOME**

*The Action at page 2 objected to claim 12 allegedly for the term "be hydrogen" has been recited twice.*

Applicants appreciate the Examiner's noting of the typographical error, and have corrected claim 12 as requested. Applicants respectfully ask that the objection now be withdrawn.

**2.5    OBJECTION TO CLAIMS 3 AND 15 UNDER 35 U. S. C. § 1.75(C) IS OVERCOME**

*The Action at page 2 objected to claims 3 and 15 allegedly as being of improper dependency form.*

Applicants respectfully traverse. Nevertheless, mindful of patent term, and in the interest of advancing certain claims to allowance and to avoid the expense of a protracted prosecution, Applicants have amended claim 3 to place it in proper dependency from claim 1. With respect to claim 15, the issue is now moot as the claim has been canceled in the accompanying amendment.

Applicants respectfully request that this objection be withdrawn.

**2.6    REJECTION OF CLAIMS 1, 3-13, 15-17, 19, AND 25-28 UNDER 35 U. S. C. § 112, 1<sup>ST</sup> PAR., IS OVERCOME.**

*The Action at page 3 rejected to claims 1, 3-13, 15-17, 19, and 25-28 under 35 U. S. C. § 112, 1<sup>st</sup> paragraph, allegedly because the specification lacks enablement across the breadth of the pending claims.*

The Office has rejected claims 1, 3-13, 15-17, 19, and 25 to 28 allegedly because the Specification, while being "enabling for a complex of formula I in instant claim 1 for D being piperacillin....does not reasonably provide enablement for complexes with any drug or biological molecule as broadly claimed."

Applicants respectfully traverse, and respectfully note that all that is required to comply with 37 C. F. R. § 112, 1<sup>st</sup> paragraph, is for the Specification to teach how to make and use the claimed invention so that it may be practiced without undue experimentation (*In re Borkowski and Van Venrooy*, 164 USPQ 642 [C.C.P.A. 1970]). Clearly, the Specification meets this requirement, as it illustrates the materials, methods, and even experimental protocols that may be

used to not only prepare the lipoamino acid- and lipoamino saccharide-based delivery compounds, but has also taught how to use these novel delivery vehicles with a broad range of pharmaceutical and therapeutic drugs. The requirements for "how to make" and "how to use" have obviously been satisfied in the instant application.

The Examiner is reminded that in assessing the question of whether undue experimentation would be required in order to practice the claimed invention, the key term is "undue," not "experimentation." *In re Angstadt and Griffin*, 190 USPQ 214 (C.C.P.A. 1976). The need for *some* experimentation does not render the claimed invention unpatentable under 35 U. S. C. § 112, 1<sup>st</sup> paragraph. The M. P. E. P. and established case law also support Applicant's position on experimentation. M. P. E. P. § 2164.01 cites *M.I.T. v. A.B. Fortia*, 227 USPQ 428, for the proposition that even if experimentation is complex, this does not necessarily make it undue, if the art typically engages in such experimentation. The guidance from the courts is further embodied in the M. P. E. P. § 2164.04, where it is stated that if this [examination] procedure is not followed, there would be no need for the Applicant to go to the trouble and expense of supporting his presumptively accurate disclosure. Indeed, a considerable amount of experimentation may be permissible if such experimentation is routinely practiced in the art. *In re Angstadt and Griffin, supra; Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 18 USPQ 2d 1016 (Fed. Cir. 1991).

Applicants respectfully submit that the examples provided in the specification clearly satisfies the "make and use" requirement of the statute,. Moreover, the present Specification clearly provides the required nexus between what was known in the art (e.g., the difficulty in delivering a broad range of therapeutic molecules to an animal) and what was unknown prior to the teachings of the instant application (e.g., the creation of novel lipoamino acid- and lipoamino saccharide-based drug delivery compounds which are particularly useful in the delivery of therapeutic molecules to an animal, and to humans in particular). The instant application

answers these questions and overcomes the limitations in the art by providing novel compositions and methods that address such long felt needs in the art.

## **2.7 A STATUTORY THIRD-PARTY DECLARATION UNDER 37 C. F. R. § 132 IS PROVIDED**

To further address the Examiner's concern regarding a potential perceived lack of enablement in the present Specification, Applicants have provided a third-party Statutory Declaration (attached as an Exhibit hereto) prepared and executed by Professor William Roy Jackson, holder of The Sir John Monash Distinguished Professorship in the School of Chemistry at Monash University. Dr. Jackson has published more than 350 scientific papers in a career spanning more than forty years of academic research and teaching in the field of chemistry. Prof. Jackson is well-known in the Applicants' field of study, and is highly regarded by his peers as a distinguished researcher in the field of chemistry. Evidence of Prof. Jackson's extensive credentials is provided in the *curriculum vitae* attached to his declaration as **Exhibit WRJ1**. This *vitae* clearly demonstrates Prof. Jackson to be well-suited for the purpose of addressing the specific concerns of the Examiner regarding enablement on a scientific basis. Furthermore, Prof. Jackson's lengthy career in this art particularly qualifies him to address issues such as what the skilled artisan knew in this particular area of the chemical arts at the time the priority application was filed, and to critically review the instant Specification and claims, and to provide his expert opinion concerning the issues raised by the Office regarding enablement.

In this extensive Statutory Declaration by Professor Jackson, the Applicants have provided impartial and objective testimony from a disinterested third party; one who would clearly and unambiguously be considered "one of skill in the art" in the field relevant to the instant invention.

Dr. Jackson states in paragraph 2 of his statutory declaration that he has no financial interest in the present application, but was compensated for his time in reviewing the materials and in executing the declaration.

Dr. Jackson describes in paragraph 3 and 4 of the declaration the materials he has personally reviewed in conjunction with the preparation of the declaration, and in paragraph 5 states his understanding of the Examiner's concern for a perceived lack of enablement for the captioned application. Professor Jackson states in paragraph 6 of his declaration that he disagrees with the Office's assessment that the Specification "does not provide sufficient teaching to enable one of skill in this field to prepare and use the lipoamino acid - and lipoamino saccharide-based compounds" as drug delivery vehicles."

In paragraph 7 of his declaration, Prof. Jackson states unambiguously that it is his scientific opinion that one of skill in the art *would*, in fact, *be able to make and use the compounds and compositions as taught by the specification* commensurate in scope with what has been claimed, and that the disclosed novel and non-obvious drug delivery vehicles would be expected to perform as the Specification teaches, and that these compounds would be useful in the delivery of a broad range of therapeutic molecules as set forth in the Applicants' Specification.

Prof. Jackson's statutory declaration contradicts the Office's position that it would take one of skill in the art "undue experimentation" in order to practice the invention over the entire scope of the invention as presently claimed. In paragraph 8 he notes that in addition to single drug piperacillin that the Office has admitted is clearly enabled, the Applicants' Specification has also taught how to make and use the novel drug delivery agents as carriers for other therapeutically-useful compounds that are chemically and structurally unrelated to piperacillin.

For example, Prof. Jackson points to page 71 of the Specification, and concludes that this portion of the Specification provides the requisite teaching for use of these delivery vehicles as

carrier molecules for gentamycin sulfate and related aminoglycoside antibiotics. Furthermore, Prof. Jackson concludes that because of the detailed teaching of the Specification, one of skill in the art *would not require undue experimentation* in order to utilize the disclosed drug delivery vehicles as taught in the captioned patent application.”

In paragraph 9 of his statutory declaration, Prof. Jackson further states that Example 18 of the Specification further supports his position, and notes that this Example provides a teaching of how to make and use the disclosed carrier molecules to improve the bioavailability of heparin and related heparinoid, sulfated, and acidic oligosaccharides. Once again, because these compounds are chemically and structurally unrelated to the other compounds taught in the Specification, the Declarant concludes that the Applicants have demonstrated success of their invention as carrier molecules for a diverse range of chemical drug species.

The Declarant also states in paragraph 10 that he disagrees with the Office’s position that the instantly-claimed invention is “highly unpredictable.” To support his position, he points to several passages in the Specification (e.g., page 13) that, in his scientific opinion, would clearly satisfy the enablement requirement by “teaching one of skill in the art how to make and use the invention” commensurate in scope with that claimed in the present application.

The third-party Declarant concludes his statement in paragraphs 11 and 12 of the attached document by stating that in his scientific opinion, a skilled artisan, having benefit of the teachings of the instant Specification, combined with the general knowledge in the art that was available contemporaneous with the filing date of the priority application, would be able to practice the Applicants’ invention without undue experimentation, and that there would be a reasonable expectation of success of achieving such results if the skilled artisan were to employ the novel teachings of the application to prepare and use the claimed compounds as drug delivery vehicles to increase the bioavailability or delivery of a broad range of therapeutic molecules.

Thus, in consideration of the extensive third-party declaration by Dr. Jackson, Applicants respectfully reiterate their belief that the present rejection under 37 C. F. R. § 112, 1<sup>st</sup> paragraph, is improper, and that the rejection should be withdrawn.

As such, Applicants respectfully request the Examiner's concurrence with their position and seek withdrawal of the rejection based upon the present submission and that all claims be in condition for allowance.

## **2.8 REQUEST FOR EXAMINER INTERVIEW**

Pursuant to M. P. E. P. § 713.01 and 37 C. F. R. § 1.133, Applicants hereby request an interview with Applicants' undersigned representative in order to facilitate an expeditious conclusion of prosecution on the merits in the present application, and to permit expedited allowance and issuance of the pending claims prior to the issuance of a first action on the merits in the Request for Continued Examination filed herewith.

Consistent with M. P. E. P. §§ 408 and 713.09, Applicant requests that the Examiner contact the undersigned representative within the next 30 days to arrange a telephonic Examiner Interview at a mutually convenient time to discuss favorable disposition of the case and the resolution of the issues of record as soon as he has had the opportunity to review and consider the present paper, and before issuance of a first action on the merits in the RCE.

## **2.9 CONCLUSION**

It is respectfully submitted that all claims are fully enabled by the Specification, and that all claims are definite, and free of the prior art. Applicants believe that the claims are acceptable under all sections of the Statutes and are now in conditions for ready allowance, and that all of the concerns of the Examiner have been resolved. Applicants earnestly solicit concurrence by the Examiner and the issuance of a Notice of Allowance in the case with all due speed.

Applicants note for the record their explicit right to re-file claims to one or more aspects of the invention as originally claimed in one or more continuing application(s) retaining the priority claim from the present and parent cases.

Should the Examiner have any questions, a telephone call to the undersigned Applicants' representative would be appreciated, and in particular in advance of any subsequent action on the merits.

Respectfully submitted,



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